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ORIGINAL ARTICLE

# High rate of fracture in the cementless modular Extrême<sup>TM</sup> (Mark I) femoral prosthesis in revision total hip arthroplasty: 33 cases at more than 5 years' follow-up



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## KEYWORDS

Femoral loosening;  
Revision total hip arthroplasty;  
Interlocking femoral stem;  
Modular femoral stem;  
Femoral stem subsidence

## Summary

**Introduction:** The modular concept has been recommended in femoral revision surgery with extensive bone loss, but entails mechanical complications: disassembly and fracture. The present retrospective study assessed the Mark I Extrême<sup>TM</sup> modular prosthesis at a minimum 5 years' follow-up.

**Hypothesis:** A cementless modular femoral stem facilitates revision in case of extensive bone loss, providing satisfactory results without risk of junction failure.

**Materials and methods:** Thirty-three prostheses presenting aseptic loosening, including 3 with periprosthetic fracture, in 23 female and 9 male patients, with a mean age of 65 years (range, 49–83 years), were reviewed at a mean 6.3 years' follow-up (range, 5–9 years). Bone loss was assessed on the SOFCOT (17/33 grade 3 or 4) and Paprosky classifications (19/33 grade III or IV). One patient died; another was lost to follow-up, leaving 31 hips for analysis. Clinical assessment comprised Postel Merle d'Aubigné (PMA) and Harris Hip scores (HHS); radiological assessment used the Engh score and corticomedullary index (CMI).

**Results:** There were 15 complications requiring surgery: 9 (27%) unrelated to the implant (1 hematoma, 2 infections, 2 dislocations, 1 femoral non-union, 3 asymptomatic trochanteric non unions) and 6 (18%) implant-related (four 3-level fractures and 2 epiphyseal-metaphyseal disassemblies, requiring 3 total exchanges and 3 proximal component replacements). PMA and HHS scores showed significant improvement, PMA rising from 10.4 (6–18) to 14.4 (11–18) and HHS from 50 (19–88) to 80.9 (52–100). Bone regrowth was "certain" on the Engh classification in 11 cases (44%). There was no diaphyseal component subsidence, even in case of fracture or dissociation. CMI at the 3 junctions between the 4 quarters of the stem showed no significant change: 32.9 and 32.7, 41.2 and 38.7, and 41.6 and 39.9 respectively. Six-year survivorship was 81% (95% CI: 68–94%).

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**Discussion:** In other series for the same type of implant, the rates of fracture (always metaphyseal-diaphyseal) were much lower: 0.8–3.8%. This stem ensures diaphyseal fixation in case of extensive bone loss, but incurs excessive risk of disassembly and fracture.

**Level of evidence:** Level IV, retrospective study.

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## Introduction

Modularity has been recommended in femoral revision arthroplasty with extensive bone loss [1–10]. Diaphyseal components, or “nails”, of various lengths and diameters and metaphyseal-epiphyseal components of various sizes enable a truly tailor-made implant to be produced, ensuring diaphyseal anchorage and adjusted length, anteversion and offset. These recognized advantages [1–10] are, however, counterbalanced by fracture rates between 0.8% [5] and 3.8% [6], and design, metallurgy and assembly demand particular care [3,6–8].

A retrospective series of 33 revision arthroplasties for severe aseptic loosening used the Extrême™ Mark I modular implant, with a hydroxyapatite (HA) coating and locking mechanism of proven efficacy [1–6,8–10]. Functional results and fixation were assessed at a minimum 5 years’ follow-up and the mechanical failure rate was compared with the literature data.

## Materials and methods

### Patients

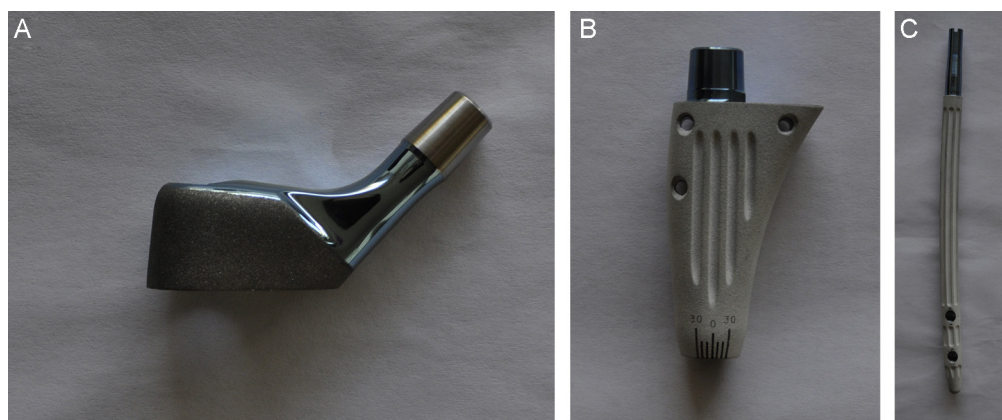
Between 2002 and 2006, 33 femoral replacements were performed in 23 female and 9 male patients with a mean age of 65 years (range, 43–75 years). Initial etiology was: congenital dysplasia ( $n=19$ ), primary osteoarthritis of the hip ( $n=7$ ), osteonecrosis ( $n=3$ ), rheumatoid coxitis ( $n=2$ ), or post-traumatic osteoarthritis of the hip ( $n=2$ ). In 11 cases, the operation was the first revision procedure, in 9 the

second and in 13 the third or more. The indication was systematically aseptic loosening (bipolar in 18 cases and femoral in 15). The implicated stem was standard in 26 cases (including 23 cemented stems) and long in 7 (including 5 cemented stems), with severe osteolysis in 24 cases and periprosthetic fracture in 3. The cup was loose and/or worn in 18 cases. The Extrême™ model was chosen when the longest monoblock model in use at the time (260 mm) failed to ensure a minimum 10 cm anchorage in the healthy femur – which is why Extrême™ implants were used in only 33 out of 289 procedures (11.4%) performed during the study period.

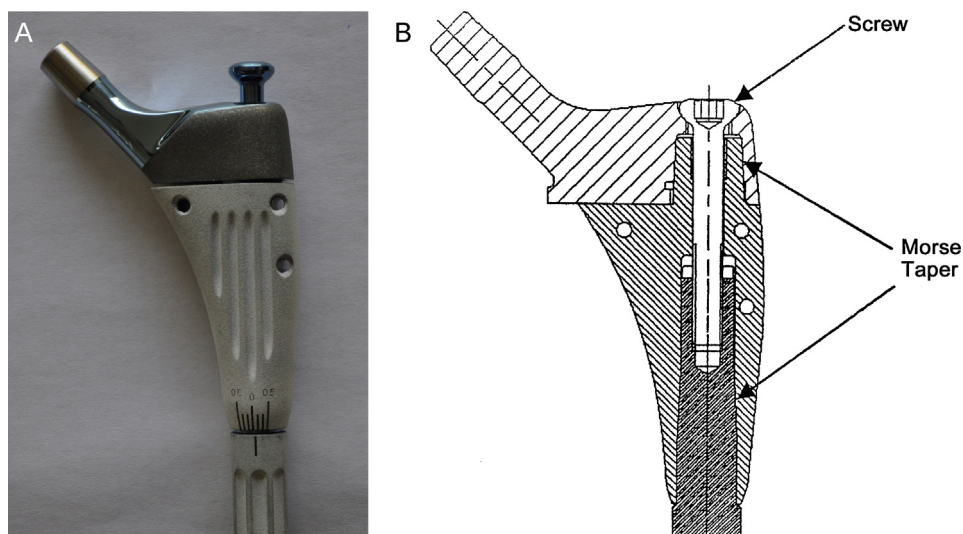
### Materials

The Extrême™ I stem (Amplitude, Valence, France) comprised 4 parts: epiphyseal and metaphyseal, both in 4 sizes, diaphyseal nail (diameter, 10–20 mm in 2-mm increments; length, 200–400 mm in 50-mm increments), and head (Fig. 1). The first 3 components (in titanium alloy coated in HA, except for the epiphyseal component) were assembled by double Morse taper secured by a screw (Fig. 2). Version was adjustable by 20° at both junctions.

Three surgical approaches were used by 6 surgeons: intrafemoral ( $n=3$ ), trochanterotomy ( $n=5$ ), and extended trochanteric osteotomy ( $n=25$ ) (ETO) with a mean length of 18.3 cm (range, 4–31 cm). The nail was selected for maximal filling, according to the diameter of the last reamer to be used (or 1 mm less), and was anchored in a friction cylinder about 10 cm long. The metaphyseal component was then selected so as to be in contact with the medial part of



**Figure 1** Extrême I™ implant: epiphyseal component (A), metaphyseal component (B) and nail (C).



**Figure 2** Epiphyseal-metaphyseal assembly (A and B).

the metaphysis and then the epiphysis and head with adequate length and offset. Anteversion was adjusted at the epiphyseal-metaphyseal junction, and the nail was locked by 2 distal screws using a proximally fixed jib. The fixation screw of the two tapers was tightened using a dynamometric screwdriver. Two counter-femorotomies were required to bring the medial femur in contact with the metaphyseal component. Partial bone-graft filling was performed in 5 cases.

### Assessment

Charnley grade [11], Devane score [12], ASA (American Society of Anesthesiologists) score and body-mass index (BMI) were recorded. Function was assessed on Postel Merle d'Aubigné (PMA) [13] and Harris Hip scores (HHS) [14]. Radiological assessment was performed by 2 independent observers (JB and DH) on AP and lateral pelvic and femoral X-ray.

Preoperative bone loss was estimated on the SOFCOT [15] and Paprosky [16] classifications, and periprosthetic fracture on the Vancouver classification [17].

Stem migration beyond a threshold of 5 mm and/or 3°, radiolucency and reactive lines in the Gruen zones [18] were investigated and the Engh score was determined [19]. Corticomedullary index (CMI) following Barnett and Nordin [20] (thickness of the 2 cortical bones/medullary cavity width  $\times$  100) was measured at the 3 junctions between the 4 quarters of the stem (proximal to distal) at 3 months and last follow-up, to assess bone ingrowth. Any cortical reaction at the level of the screws was recorded. Trochanterotomy and ETO fusion were assessed.

### Statistics

The Wilcoxon test was used to compare matched values and the Mann-Whitney for non-matched values. The significance threshold was set at  $P=0.05$ . Kaplan-Meier survivorship was calculated with fracture or disassembly as event, with

the 95% confidence interval. Statistical analysis used the MedCalc™ package v.12.2.1 (Medcalc Software, Ostend, Belgium).

### Results

The 32 patients (33 hips) showed Charnley grade A in 11 cases, B in 19 and C in 2. Activity levels were low: 14 Devane grade II, 15 grade III and 3 grade IV [12]. Mean BMI was 26.8 (17.9–36.3), and mean ASA score 1.9 (1–3).

In the 30 cases without fracture, bone loss was categorized as:

- 9 cases of SOFCOT [15] grade 1, 4 grade 2, 13 grade 3 and 4 grade 4;
- 3 cases of Paprosky [16] grade I, 8 grade II, 13 grade IIIA, 3 grade IIIB and 3 grade IV.

There were 2 cases of preoperative trochanteric non-union.

In grades 1(I) and 2(II), the Extrême™ implant was required for the length of the ETO needed to remove the existing implant and/or cement.

Two of the 3 periprosthetic fractures were graded B2 and the third B3 [17].

Mean nail diameter was 13.6 mm (range, 12–18 mm), providing optimal filling of the diaphysis; mean length was 285 mm (range, 250–400 mm). The socket was replaced in 18 cases. Mean follow-up was 6.3 years (range, 5–9 yrs). One patient was lost to follow-up at 17 months and a second died at 2 years, without complications, leaving 31 hips in 30 patients for analysis.

There were 9 complications unrelated to the implant:

- 1 hematoma, treated on revision;
- 2 infections which resolved in 1 case at 18 months after lavage and antibiotherapy (the stem subsequently broke at the metaphyseal-diaphyseal junction at 5 years: case no. 1, see Table 1), and in the other at 4 years after lavage

**Table 1** Details of the 6 cases of fracture/disassembly.

Case	Age (yrs)	Sex	BMI	BL	Stem diameter (mm)	Approach	Months to fracture (F) or disassembly (D)	Level	Evolution
1	66	F	21	4/IV	16	ETO	21	F proximal locking hole	Repeat fracture (60 months)
2	72	F	30.1	3/IIIA	12	ETO	76	F metaphysis-diaphysis	
3	69	M	33.9	3/IIIA	16	ETO	14	F proximal locking hole	
4	71	F	27.5	3/IIIB	14	ETO	73	F epiphysis	
5	50	M	30	2/IIIA	14	Trochanterotomy + ETO	58	D epiphysis-metaphysis	
6	65	F	28	3/IIIA	14	Posterior	72	D epiphysis-metaphysis	

BL: bone loss according to SOFCOT [15] and Paprosky [16] (SOFCOT/Paprosky); BMI: body-mass index; ETO: extended trochanteric osteotomy.

and antibiotherapy (epiphyseal-metaphyseal disassembly occurred at 5 years: case no. 5, see Table 1);

- 2 posterior dislocations, at 2 months and 3 years respectively, managed conservatively after close reduction;
- 3 new cases of asymptomatic trochanteric non-union, not requiring revision;
- and 1 ETO non-union, successfully managed by cerclage and autograft, at 1 year.

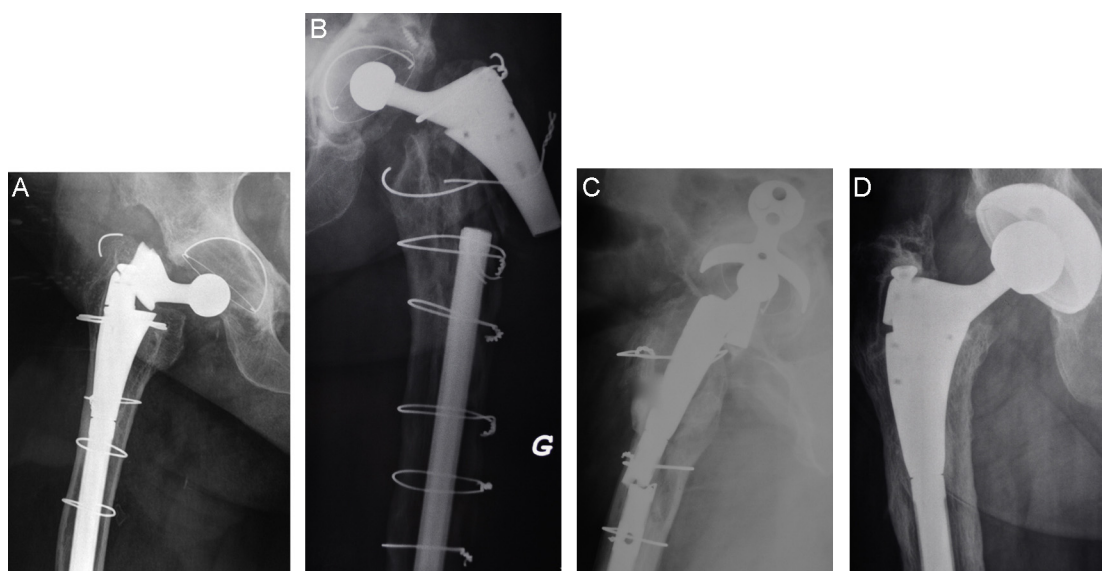
The cases of mechanical failure were more serious (Table 1, Fig. 3):

- 4 fractures (12.9%) (Table 1), at a mean 46 months (range, 21–73 months), at 3 levels:
  - 1 epiphyseal (Fig. 3A),
  - 1 of the metaphyseal-diaphyseal junction taper (Fig. 3B),

- and 2 of the proximal locking (Fig. 3C).

In all 4 cases, the metaphyseal component lacked osseointegration. The fractured epiphyseal component was replaced. In the other 3 cases, the nail was integrated, causing problems of extraction: the metaphyseal-diaphyseal fracture was managed using a Linea™ monoblock implant (Tornier, St Ismier, France) and the 2 fractures at the most proximal locking hole were managed using a second Extrême™ I implant (one of which in turn fractured at the metaphyseal-diaphyseal junction, and was replaced by a Linea™ implant).

Two epiphyseal-metaphyseal disassemblies (Fig. 3D) at 5 years (6.4%), managed in 1 case by replacing the epiphyseal component and in the other by fitting a monoblock epiphyseal-metaphyseal component (Extrême™ Mark II).



**Figure 3** Types of mechanical failure; A: epiphyseal fracture; B: metaphyseal-diaphyseal fracture; C: fracture at locking hole; D: epiphyseal-metaphyseal disassembly.



**Table 2** Evolution of Postel Merle d'Aubigné score (PMA) [13] according to Paprosky bone loss grade [16].

	Preop PMA	PMA at end of FU
Grade < III	10.50 (6–17)	14.75 (7–18)*
Grade ≥ III	11.30 (7–16)	14.4 (10–18)*

\*Significant difference.

Four patients (12%) suffered discomfort around the locking screws, which were too long for these thin subjects; the screws were shortened in 2 cases and removed in 4, at 6–20 months.

Six-year survivorship with fracture or disassembly as event was 81% (95% CI: 68–94%). Twenty-five stems (in 24 patients) were intact at more than 5 years; PMA [13] and HHS [14] scores showed significant improvement, from 10.4 (range, 6–18) to 14.4 (11–18) ( $P < 0.05$ ) and from 50 (19–88) to 80.9 (52–100) ( $P < 0.05$ ) respectively, irrespective of bone loss (Table 2). On the Engh classification [19], osseointegration was “certain” (score,  $\geq 10$ ) in 11 cases and “fibrous” ( $< 10$ ) in 14. There were reactive lines (zone 6:  $n = 4$ , 16%) and radiolucency (zone 2:  $n = 11$ , 44%; zone 13:  $n = 7$ , 28%) at the metaphyseal-diaphyseal junction. None of the nails, whether fractured or not, migrated. CMI [20] showed non-significant decrease ( $P > 0.05$ ) between 3 months and end of follow-up at the 3 proximal-to-distal levels, from 32.9 to 32.7, 41.2 to 38.7 and 41.6 to 39.9 respectively.

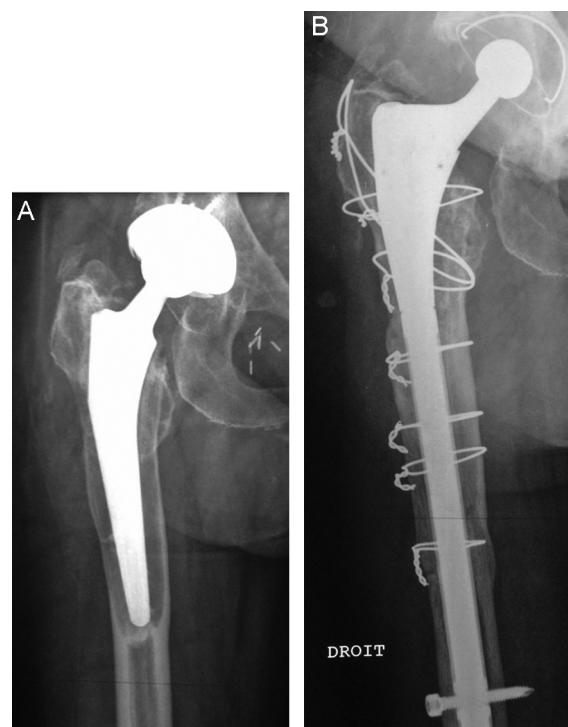
All 3 periprosthetic fractures showed fusion, as did 24 out of 25 ETOs. There were 3 cases of trochanteric non-union, on top of the 2 per-operative cases. Cortical hypertrophy around the locking screws was found in 9 cases (36%), without correlation with pain (mean PMA, 15.4 and 14 with and without hypertrophy, respectively) or with mechanical complications.

## Discussion

Results for surviving implants were satisfactory (PMA = 14.4), without diaphyseal migration, but the rates of fracture (12.9%) and disassembly (6.4%) were so excessive that we abandoned the Extrême™ I implant.

The present study had strong points (single implant model, single indication, 94% follow-up) and weak points (6 surgeons, 3 types of approach, and only 33 cases). The number of surgeons is explained by the length of the study period (5 years) and the university hospital setting, although no learning-curve effect was detectable in the younger surgeons. The most frequent approach was ETO (25 cases), allowing material extraction and stem implantation without impairing secondary fixation (on condition that there was contact between cortical bone and HA coating), unlike our experience with trochanterotomy (3 non-unions out of 5 procedures), which we abandoned.

Osseointegration was judged “certain” (Fig. 4) in only 44% of cases, compared to 85–98% in other reports [1,2,4,5,9,10]. This may have been due to differences in radiographic assessment. At all events, there would seem to have been no cases of failed osseointegration:



**Figure 4** Favorable evolution without fracture; A: preoperative condition (SoFCOT grade 4, Paprosky grade IIIB); B: results at 9 years, with osseointegration and proximal bone reconstruction.

- surviving implants were never associated with pain, suggesting good fixation;
- there was no nail migration, and ablated nails showed osseointegration;
- reactive lines and radiolucency were partial and situated at junctions where they could be accounted for by release of metal microparticles [6,7,21,22].

Cortical hypertrophy around screws (36% of the present cases) could suggest non-osseointegration with transmission of stress to the distal part of the stem [23]; but this is unlikely, as it did not correlate with pain or mechanical complications. Unlike Miletic et al. [24], the present series showed no significant improvement in CMI.

The most striking feature of the present results was the abnormally high rate of fracture/disassembly, at 3 levels. The literature reports only cases of fracture, systematically at the metaphyseal-diaphyseal junction, and at rates of 0.8–3.8% [1–6,8–10] (Table 3). This difference may be due to the poor mechanical resistance of the Extrême™ I model, more extensive bone loss than in all but 2 [1,6] of the other series and a longer follow-up (6.3 years, with 3 of the 6 cases of mechanical failure occurring beyond 5 years) (Table 3). Some reports have implicated BMI > 30, Paprosky bone loss of grade III or IV and too small a nail [2,3,5,7–9,25]; the present results, however, failed to identify any risk factors (including extent of bone loss) (Table 1).

There have been studies of metaphyseal-diaphyseal fractures in modular pivots [7,26]:

**Table 3** Literature data on modular revision implants.

Authors	Implant	Number of cases	Mean FU (months)	Fracture (%)	Loosening
Garbuz et al. [8]	ZMR™	31	<24	3.2	ND
Rodriguez et al. [9]	Link MP™	97	45	1.0	5.0%
Ovesen et al. [5]	ZMR™	125	50	0.8	ND
Richards et al. [6]	TFMT™	95	37	3.8	0.9%
Philippot et al. [1]	REEF™	43	58.2	2.3	ND
Restrepo et al. [10]	RMS™	120	48	0.0	0.0%
Mertl et al. [2]	Multiple types of locked stems	725	54	1.4	ND
Lakstein et al. [7]	ZMR™	179	>24	3.4	ND
Current series	Extrême™ I	31	76	16.1	00%

ND: no data.

- this junction is subject to considerable mechanical stress, which is increased by 93% in case of non-union of ETO and by 82% in case of metaphyseal non-osseointegration [26]. To reduce stress, metaphyseal osseointegration should be enhanced by a metaphyseal filling component (which complicates ETO reduction) or by bringing the bone up against the implant (medial osteotomy [2]);
- cyclic loading generates micromovements in the junctions, inducing fretting corrosion, with metal particle release and taper fissuring followed by fatigue fracture [7,21,22,26]. Titanium is particularly subject to this phenomenon, especially in an aqueous environment [7,22].

The level of mechanical stress also accounts for the other sources of mechanical failure:

- fracture of what may have been too fragile an epiphysis (1 case), resolved in the Mark II Extrême model;
- fracture of the nail at the most proximal locking hole (2 cases). According to Mertl et al. [2], locking holes, when not used, are weak zones. In the current series, we never used the proximal locking holes, which may have induced these fractures. Even so, their presence in this high-stress area is open to criticism;
- disassembly of the proximal screw (2 cases), possibly due to insufficient tightening or fixation.

In 2006, following reports of mechanical incidents, the Amplitude company and the French health products safety agency (ANSM, formerly AFFSAPS) put out an alert, blaming poor junction impaction. The company recommended bench assembly or assembly under visual control. However, the nail can only be locked by means of a jib screwed into its proximal end, which precludes bench assembly in case of distal locking. Impaction under visual control necessarily requires femorotomy, as performed in the present 4 cases of fracture. The company's recommendations thus appear impracticable. The Extrême™ Mark II model differs from Mark I in its single totally coated epiphyseal-metaphyseal component. We used it 3 times, and observed 2 metaphyseal-diaphyseal junction fractures at 3 years: stress is entirely focused on this single junction, entailing a real risk of failure.

## Conclusion

The Extrême™ Mark I modular stem deals with extensive bone loss, but with an excessive risk of fracture, as found with all modular implants. Better metallurgy and osseointegration of the metaphyseal component might reduce this risk, but not entirely remove it in case of severe bone defect.

## Disclosure of interest

Denis Hutten has no conflicts of interest regarding the present study, but elsewhere receives fees from Smith & Nephew. Jean Louis Polard has no conflicts of interest regarding the present study, but elsewhere receives fees from Medacta and Zimmer. Jonathan Benoist and Jean Christophe Lambotte have no conflicts of interest regarding the present study or otherwise.

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